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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

P/37-171

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/937516

INTERNATIONAL APPLICATION NO.
PCT/EP00/02502

INTERNATIONAL FILING DATE
21 March 2000

PRIORITY DATE CLAIMED
25 March 1999

TITLE OF INVENTION

STERILIZATION CONTAINER

APPLICANT(S) FOR DO/EO/US

Peter WAGNER

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). - **unsigned**
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 16 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☒ Other items or information:

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail Post Office to Addresses (mail label **EL855849218** in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231, on **September 25, 2001**

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Dorothy Jenkins

Name of Person Mailing Correspondence

Dorothy Jenkins
Signature

September 25, 2001

Date of Signature

INTERNATIONAL APPLICATION NO.

ATTORNEY'S DOCKET NUMBER

P/37-171

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PTO/PGT Rec'd 08 MAR 2002

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P/37-171

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

4

In re Patent Application of

Peter WAGNER

Date: March 6, 2002

Serial No.: 09/937,516

Group Art Unit: ---

Int'l. Filing Date: March 21, 2000

Examiner: ---

For: STERILIZATION CONTAINER

U.S. Patent and Trademark Office

P.O. Box 2327

Arlington, VA 22202

Attn: Box PCT (US/DO/EO)

AMENDMENT/SUBMISSION

Prior to examination, please amend the application as follows.

FEE CALCULATION

Any additional fee required has been calculated as follows:

X If checked, "Small Entity" status is claimed.

NO. CLAIMS AFTER AMENDMEN		HIGHEST NO. PREVIOUSLY PAID FOR		EXTRA PRESENT		RATE		ADDIT. FEE
T								
TOTAL	25	MINUS	20	* =	5	X	(\$9 SE or \$18)	\$ 45.00
INDEP.	2	MINUS	3	** =	0	X	(\$42 SE or \$84)	\$
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					X		(\$140 SE or \$280)	\$

* not less than 20 ** not less than 3

TOTAL \$ 45.00

If any additional payment is required, a check which includes the calculated fee of \$45.00 (OFGS Check No. 08662) is attached.

In the event the actual fee is greater than the payment submitted or is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 15-0700.

CONTINGENT EXTENSION REQUEST

If this communication is filed after the shortened statutory time period had elapsed and no separate Petition is enclosed, the Commissioner of Patents and Trademarks is petitioned, under 37 C.F.R. § 1.136(a), to extend the time for filing a response to the outstanding Office Action by the number of months which will avoid abandonment under 37 C.F.R. § 1.135. The fee under 37 C.F.R. § 1.17 should be charged to our Deposit Account No. 15-0700.

AMENDMENTS

☒ If checked, amendment(s) to the specification and/or claims are submitted herewith.

1. Claims:

Please amend claims 3, 4, 6, 9, 11, 12, 14-17 and 19-25 pursuant to 37 C.F.R. § 1.121(c)(i) as set forth in the “clean” version attached hereto as Appendix A. Entry is respectfully requested. A version with markings to show the changes made pursuant to 37 C.F.R. § 1.121(c)(ii) is attached hereto as Appendix B.

REMARKS/ARGUMENT

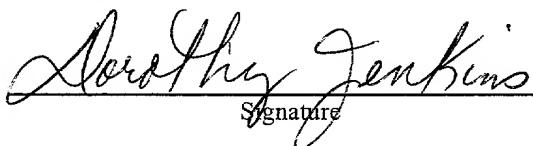
This Preliminary Amendment is being submitted to change the multiple dependent claims to single dependent claims in order to eliminate the improper multiple dependent claims and to reduce the government filing fee.

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail to Addressee (mail label # EL334669937US) in an envelope addressed to: U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, on March 6, 2002:

Dorothy Jenkins

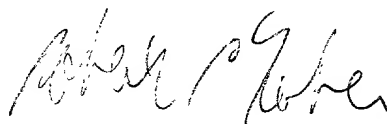
Name of Person Mailing Correspondence


Signature

March 6, 2002

Date of Signature

Respectfully submitted,



Robert C. Faber

Registration No.: 24,322

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APPENDIX A
"CLEAN" VERSION OF EACH PARAGRAPH/SECTION/CLAIM
37 C.F.R. § 1.121(b)(ii) AND (c)(i)

CLAIMS (with indication of amended or new):

(Amended) 3. The sterilization container as claimed in claim 1, in which the temperature sensor is formed by a snap-disk stack, characterized in that two snap-disk types (94, 96) having different temperature behavior are provided in a snap-disk stack.

(Amended) 4. The sterilization container as claimed in claim 1, characterized in that the valve arrangement (26, 28) is arranged as a condensate drain valve at a recessed location of the container bottom.

(Amended) 6. The sterilization container as claimed in claim 1, characterized in that the valve plate (50), in its center section, carries a housing (62, 72, 74) which accommodates the snap-disk stack (94, 96), which controls a valve ball (90) which interacts with a valve-seat ring (78).

(Amended) 9. The sterilization container as claimed in claim 1, characterized in that the lid (74) of the snap-disk housing carries a blocking spring (82) having a blocking pin (86) which, as closing lock of the valve (26, 28), interacts with a valve-cap stop (100).

(Amended) 11. The sterilization container as claimed in claim 1, characterized in that the base of the snap-disk housing carries an outlet sealing disk (68) which bears as a check valve above a ventilation opening (66) of the valve plate (50).

(Amended) 12. The sterilization container as claimed in claim 1, characterized in that the valve plate, in the space enclosed by the bellows (46), has a vent opening (56) which can be closed as a check valve by a sealing disk (58) preloaded in the sealing position by a leaf spring (60).

(Amended) 14. The sterilization container as claimed in claim 6, characterized in that the blocking pin carried by the blocking spring (82) carries the pin (88) which engages in the region of movement of the valve ball (90).

(Amended) 15. The sterilization container as claimed in claim 1, characterized in that the ventilation opening (66) leading into the interior of the snap-disk housing can be closed by a valve ball (106) which is arranged at the base of the snap-disk stack.

(Amended) 16. The sterilization container as claimed in claim 1, characterized in that the valve disk (50) has a conical baffle plate (54) as a condensate deflector under the perforation holes (22) of the container bottom.

(Amended) 17. The sterilization container as claimed in claim 2, characterized in that the snap disks (94, 96) having different temperature characteristics are arranged in pairs and have an identical curvature configuration at room temperature.

(Amended) 19. The sterilization container as claimed in claim 17, characterized in that a high-grade-steel disk (92) curved convexly upward and having an invariable curvature lies above the upper snap-disk pair (94, 96) and carries the valve ball (90) in the center part.

(Amended) 20. The sterilization container as claimed in claim 17, characterized in that the lower snap-disk pair (94A, 96A) is supported by a high-grade-steel disk (99) which is curved convexly upward and is invariable in its shape, and in that a high-grade-steel disk (98) curved concavely upward lies between the snap-disk pairs (94, 96, 94A, 96A).

(Amended) 21. The sterilization container as claimed in claim 17, characterized in that the respectively upper snap disk (94, 94A) of each snap-disk pair has a snap-over point at about 115°C during heating and snaps back under hysteresis at 95°C during cooling.

(Amended) 22. The sterilization container as claimed in claim 17, characterized in that the respectively lower snap disk (96, 96A) of each snap-disk pair has a snap-over point of more than 115°C, preferably 117°C, during heating and does not snap back under hysteresis until 35 to 50°C during cooling.

(Amended) 23. The sterilization container as claimed in claim 15, characterized in that the valve ball (106) interacting with the ventilation opening (66) is carried by the lower high-grade-steel disk (99).

(Amended) 24. The sterilization container as claimed in claim 1, characterized in that a distance piece (52) is provided between a lower annular flange (48) of the bellows (46) and the valve plate (50).

(Amended) 25. The sterilization container as claimed in claim 1, characterized in that a sealing ring (18) of L-shaped cross section is arranged between container lid (12) and trough (10), this sealing ring (18) being inserted with its radially inwardly disposed leg into a circumferential groove (20) of the container lid and interacting with a radial and horizontal annular surface of the trough top rim.

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APPENDIX B
VERSION WITH MARKINGS TO SHOW CHANGES MADE
37 C.F.R. § 1.121(b)(iii) AND (c)(ii)

CLAIMS:

3. The sterilization container as claimed in claim 1 [or 2], in which the temperature sensor is formed by a snap-disk stack, characterized in that two snap-disk types (94, 96) having different temperature behavior are provided in a snap-disk stack.

4. The sterilization container as claimed in [one of claims 1 to 3] claim 1, characterized in that the valve arrangement (26, 28) is arranged as a condensate drain valve at a recessed location of the container bottom.

6. The sterilization container as claimed in [one of claims 1 to 5] claim 1, characterized in that the valve plate (50), in its center section, carries a housing (62, 72, 74) which accommodates the snap-disk stack (94, 96), which controls a valve ball (90) which interacts with a valve-seat ring (78).

9. The sterilization container as claimed in [one of claims 1 to 8] claim 1, characterized in that the lid (74) of the snap-disk housing carries a blocking spring (82) having a blocking pin (86) which, as closing lock of the valve (26, 28), interacts with a valve-cap stop (100).

11. The sterilization container as claimed in [one of claims 1 to 10] claim 1, characterized in that the base of the snap-disk housing carries an outlet sealing disk (68) which bears as a check valve above a ventilation opening (66) of the valve plate (50).

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12. The sterilization container as claimed in [one of claims 1 to 11] claim 1, characterized in that the valve plate, in the space enclosed by the bellows (46), has a vent opening (56) which can be closed as a check valve by a sealing disk (58) preloaded in the sealing position by a leaf spring (60).

14. The sterilization container as claimed in [one of claims 6 to 13] claim 6, characterized in that the blocking pin carried by the blocking spring (82) carries the pin (88) which engages in the region of movement of the valve ball (90).

15. The sterilization container as claimed in [one of claims 1 to 10] claim 1, characterized in that the ventilation opening (66) leading into the interior of the snap-disk housing can be closed by a valve ball (106) which is arranged at the base of the snap-disk stack.

16. The sterilization container as claimed in [one of claims 1 to 15] claim 1, characterized in that the valve disk (50) has a conical baffle plate (54) as a condensate deflector under the perforation holes (22) of the container bottom.

17. The sterilization container as claimed in [one of claims 2 to 16] claim 2, characterized in that the snap disks (94, 96) having different temperature characteristics are arranged in pairs and have an identical curvature configuration at room temperature.

19. The sterilization container as claimed in [claims 17 and 18] claim 17, characterized in that a high-grade-steel disk (92) curved convexly upward and having an invariable curvature lies above the upper snap-disk pair (94, 96) and carries the valve ball (90) in the center part.

20. The sterilization container as claimed in [claims 17 to 19] claim 17, characterized in that the lower snap-disk pair (94A, 96A) is supported by a high-grade-steel disk (99) which is curved convexly upward and is invariable in its shape, and in that a high-grade-steel disk (98) curved concavely upward lies between the snap-disk pairs (94, 96, 94A, 96A).

21. The sterilization container as claimed in [one of claims 17 to 20] claim 17, characterized in that the respectively upper snap disk (94, 94A) of each snap-disk pair has a snap-over point at about 115°C during heating and snaps back under hysteresis at 95°C during cooling.

22. The sterilization container as claimed in [one of claims 17 to 21] claim 17, characterized in that the respectively lower snap disk (96, 96A) of each snap-disk pair has a snap-over point of more than 115°C, preferably 117°C, during heating and does not snap back under hysteresis until 35 to 50°C during cooling.

23. The sterilization container as claimed in [one of claims 15 and 17 to 22] claim 15, characterized in that the valve ball (106) interacting with the ventilation opening (66) is carried by the lower high-grade-steel disk (99).

24. The sterilization container as claimed in [one of claims 1 to 23] claim 1, characterized in that a distance piece (52) is provided between a lower annular flange (48) of the bellows (46) and the valve plate (50).

25. The sterilization container as claimed in claim 1 [or 2], characterized in that a sealing ring (18) of L-shaped cross section is arranged between container lid (12) and trough (10), this sealing ring (18) being inserted with its radially inwardly disposed leg into a circumferential groove (20) of the container lid and interacting with a radial and horizontal annular surface of the trough top rim.

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Abstract

The invention relates to a sterilization container with a valve arrangement that is designed in such a manner that the valve intended for the exchange of media remains open right into the venting phase and is then closed before the pressure difference is compensated for at a predetermined differential pressure and remains closed until the container is opened for the purpose of withdrawing and using the instruments contained therein. The valve is actuated via snap disk arrangement, the snap disks of which vault gradually into the opposite direction at predetermined temperatures, thereby effecting a defined valve control. A premature back-switching of certain snap disks that could be caused by a cooling-off as a result of the evaporation of the condensate is prevented by accommodating the snap disk arrangement in a thermally insulated housing.

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Sterilization container

The invention relates to a sterilization container having a valve arrangement which permits a media exchange inside a sterilizer right into the vacuum drying phase and closes in the last ventilation phase, so that the vacuum prevailing at this instant in the container interior is maintained and the container remains hermetically sealed, the valve arrangement having a valve body subjected to the flow pressure.

Such sterilization containers, as described, for example, in DE 41 11 075 C2, have the advantage that the material to be sterilized can be kept in the container for a prolonged period without the risk of contamination, since the external atmospheric pressure keeps the container hermetically closed until ventilation is effected at random. The valve body is under spring preloading, which keeps the valve in the open position until the pressure in the sterilizer increases in the last ventilation phase and presses the valve body onto its valve seat, as a result of which the vacuum prevailing in the container at the moment of closing is maintained.

In the valve arrangement, however, the valve body must be reliably prevented from being pressed onto the valve seat prematurely by the inflowing steam, since otherwise no

reliable sterilization could take place and the container could even possibly implode. It has been found that the spring preloading of the valve body in the open position cannot reliably prevent premature closing in particular when this valve body subjected to the pressure of the flow medium has a considerable surface extent. The risk of premature closing is there, depending on the load, due to the high inflow velocities. The greater the amount of material to be sterilized which is in the container, the greater is the steam consumption required in the same time. The sterilizer is subjected to a pressure increase controlled with respect to time, i.e. the pressure increases constantly in the environment of the container, and it also penetrates into the container, in which case immediate condensation takes place (gaseous-liquid phase transition releases heat). Accordingly, the container must be "resupplied" with steam, but this steam immediately condenses again, until the heating achieved by constant condensation leads to a situation in which steam can no longer condense.

Thus, if an empty container is sterilized, hardly any more steam is required on the "inside" as on the "outside" (in order to reach 134°): the valve is then not substantially loaded with flow pressure.

If a load is sterilized, substantially more steam is "consumed" on the inside - depending on the total weight and

the heat capacity of the load: thus substantially more steam - in the same time predetermined by the sterilizer - must therefore [lacuna] through the valve gap than in the empty state. In the case of larger loads, there is therefore the risk of slamming.

In the sterilization containers of the generic type, the valve control is expediently effected via at least one temperature sensor with hysteresis behavior. This temperature sensor may be provided with a snap-disk arrangement, as described in DE 41 11 075 C2. Such a sterilization container, after opening, and after removal of the sterile material, is again available for a renewed sterilization operation without manual valve actuation being necessary. In order to ensure this, the temperature sensor, after removal of the sterilization container from the sterilizer, must automatically switch back again into the original state. In temperature sensors having a snap-disk arrangement, the switching-back is effected by the hysteresis behavior of the thermobimetal. The temperature sensors with snap disks, but also other temperature sensors, are therefore designed in such a way that the switching-back is effected within a temperature range in which the vacuum valve controlled by the sensor is reliably closed, i.e. the switching-back must not be effected before completion of the ventilation phase. In snap-disk arrangements, a temperature of 30 to 50°C is

generally assumed as switch-back temperature, i.e. a temperature which is normally not achieved until after removal from the sterilizer and after cooling of the sterilization container to room temperature.

However, it has been found that these switching temperatures of preferably 35 to 40°C, under certain circumstances, may already be reached during a drying phase inside the sterilizer. This premature cooling may occur during the sterilization of heavy steel loads, since these steel loads produce very large condensate quantities, as a result of which the sensor arrangement may be wetted with condensed steam. If vacuum drying now starts, condensate is re-evaporated, resulting in energy consumption and cooling at those locations where evaporation of the moisture occurs. If such cooling is effected in the region of the temperature sensors, the end of the sterilization operation is simulated, and premature switching-back may be effected, which would result in incorrect switching of the vacuum valve.

The object of the invention is therefore to ensure reliable vacuum sealing of any desired loads of the sterilization container, even of heavy steel loads.

This object is achieved by the features specified in the characterizing part of patent claim 1, insofar as it concerns the load- or process-related problems, and by the features specified in the characterizing part of claim 2, insofar as

it concerns the load- or process-related condensation problems or the problems associated with the premature cooling of the temperature sensor.

The thermal screening also produces reliable screening against moistening due to condensate dripping down and leads to insulation, as a result of which the existing temperature sensors follow the saturated-steam curve in a virtually ideal manner, i.e. cooling to room temperature is effected essentially by convection alone. Instead of the arrangement of the temperature sensors from above/outside on the valve body, the sensors are shifted into the interior of the gas space of the bellows. This results in perfect screening against moistening due to condensate dripping down.

The complete sensor, after switch-on is effected, is now also shut off in a gas-tight manner with respect to the bellows space. The recoil temperature of C.95° prevails in the sensor space at this instant, so that the temperature sensor cannot continue to cool down inside the sensor space (evaporation can no longer take place); the sensor space itself "conserves" a comparatively high temperature of 95° during the entire drying. As a result, it becomes possible to carry out the vacuum drying for as long as desired in a vacuum which is as low as desired without the recoil temperature being reached prematurely inside the sensor

space. As a result, premature undesirable switching of the sensor is reliably prevented.

According to a preferred embodiment, which is explained in more detail with reference to the drawing, the temperature sensor preferably provided with snap disks is shifted into the interior of the gas space of a bellows, which results in perfect screening against moistening and heat. In this case, measures are taken which direct the ventilation through the temperature final control element.

This results in the advantage that any desired load of the sterilizer can be dried for as long as desired without the described premature cooling of the temperature sensors being able to lead to a malfunction.

In sterilization technology, work is carried out at different sterilization temperatures of, for example, either 120°C or 134°C. The sterilization containers have hitherto been equipped with temperature sensors which were adapted only to one of the two common sterilization temperatures and in which malfunctions could not be ruled out if sterilization was carried out with an unmatched steam temperature.

The object of the invention is therefore to also provide a sterilization container having a valve arrangement which reliably carries out the desired switching operations and irrespective of the steam temperature at which sterilization is carried out.

This object is achieved by the features specified in the characterizing part of patent claim 3. The design and arrangement of the snap disks follow from further subclaims and the exemplary embodiment described with reference to the drawing.

The valve arrangement according to the invention may be arranged at any location in the sterilization container, i.e. in the lid or on the side walls of the trough. However, the valve is preferably arranged at the lowest point at the bottom of the trough in such a way that, during the sterilization operation, during which the vacuum valve is open, the condensate water can thus flow off. The draining of condensate therefore permits drying of the container contents without the need for energy-consuming re-evaporation of the condensate. Only in this way does it become possible to produce sterilization containers without having to take into account the thermal conductivity or heat capacity of the material used, so that, for example, containers made of plastic may also be used.

Exemplary embodiments of the invention are described below with reference to the drawing, in which:

Fig. 1 shows a vertical section of a sterilization container designed according to the invention;

Fig. 2 shows a view of the trough of the sterilization container according to fig. 1 (in the right-hand part

as viewed from above, in the left-hand part as viewed from below);

Fig. 3 shows a detail, drawn on an enlarged scale and designated by X in fig. 1, of the lid seal;

Fig. 4 shows a side view of the valve, inserted into the bottom of the trough, in the open position;

Fig. 5 shows a sectional view, drawn on an enlarged scale, of the valve-control device in the position according to fig. 4;

Fig. 6 shows a perspective view of the cover plate, carrying the control members, of the valve-control device;

Fig. 7 shows a perspective view of the outlet seal of the valve-control device;

Fig. 8 shows a view of the valve body shifted into the open position against a stop;

Fig. 9 shows, on an enlarged scale, a view corresponding to fig. 8;

Fig. 10 shows the valve-control device in a view after a temperature increase to a first temperature (of, for example, 115°C);

Fig. 11 shows the valve-control device in a sectional view during a temperature increase after reaching a second temperature (of, for example, 117°C);

Fig. 12 shows a sectional view of the valve-control device after a cooling phase;

Fig. 13 shows a sectional view of the valve in the closed position;

Fig. 14 shows a sectional view of a second embodiment of the valve-control device in an operating position according to fig. 5;

Fig. 15 shows a sectional view of the valve-control device according to fig. 14 in the valve closed position according to fig. 13.

The sterilization container consists of the trough 10 and the lid 12. The trough has a sloping bottom 14 and an encircling base frame 16. A sealing ring 18 of L-shaped cross section is arranged between the top rim of the trough 10 and the lid 12. This sealing ring, with its inwardly pointing leg, is captively inserted into an encircling groove 20 of the lid 12 and effects a seal downward and outward. The sealing ring 18 accordingly has positive locking in the horizontal, so that adhesive bonding need not be effected, but rather the seal can be exchanged on the spot without any effort. Even if the seal "sticks" slightly to the trough after prolonged mounting, the positive locking enables the lid to be removed without the seal being released from the latter. The seal has a double sealing seat: end-face contact on the one hand (especially at first - when the container is not under vacuum but is only closed with the fasteners), but, when the pressure force is increased (when the pressure

difference builds up), specific displacement of the seal into the cavity, enclosed in an encircling manner, in such a way that the vertical surfaces also become tight.

In the deep-set center section, the trough 10 has perforation holes 22 which serve for the media exchange and the outflow of the condensate. A valve arrangement 24 is provided in this center region of the container bottom 14, this valve arrangement 24 having a sealing ring 26 which interacts with an annular valve seat 28 which is formed by the bottom of the trough and lies outside the perforation holes 22, so that the container contents are sealed off from the outside atmosphere after the valve 26, 28 has been closed. The sealing ring is carried by a valve plate subjected to the flow pressure and forms the valve body together with this valve plate.

As can be seen from fig. 1, the trough bottom 14 has, in the region of the valve arrangement 24, a conical wall section 30 with the perforation holes 22. It is designed in such a way that the valve arrangement can be accommodated above the base area of the base frame 16. Formed in the central flat section 32 is a hole 34 into which a valve cap 36 is inserted from below, this valve cap 36 consisting of a rotationally symmetrical high-grade-steel part and being mechanically secured to the wall section 32 by means of a rotary-lock fastener 38 and by means of a circlip 40. The

rotary-lock fastener 38 is an oval rotatable fastener which is held on the valve cap by means of the circlip 40. After the rotary lock 38 is turned by 90°, the valve cap 36 is arrested on the trough bottom. Latching is effected by raised heads 42. A valve-cap flange 44 running under the flat section 32 is welded all-round at the bottom in a gas-tight manner to an axially compressible bellows 46. An outwardly directed annular flange 48 at the lower end of the bellows 46 is welded via an intermediate ring 52 to the valve plate 50 made of high-grade steel. The valve plate 50 carries the sealing ring 26 at its outer periphery. A baffle plate 54 running conically outward and downward under the perforation holes 22 is put onto the valve plate, so that condensate dripping out of the perforation holes 22 is diverted outward and does not collect on the valve plate 50. The valve sealing ring 26 is made of an elastomer, e.g. silicone, and is adhesively bonded or vulcanized in place on the valve plate 50.

This sealing ring could also be put on the valve seat 28 on the bottom of the trough. The valve plate 50 has a vent opening 56, which is closed by a sealing disk 58, which is pressed on in a sealing manner by a leaf spring 60 welded to the valve plate 50. These parts act as a check valve which permits venting of the valve interior space, i.e. of the space inside the bellows 46. Inside the space enclosed by the

bellows 46, a bowl 62 provided with an internal thread is welded in place on the valve plate 50. The base of this bowl 62 has a center opening 64 which is in alignment with a ventilation opening 66 in the valve plate 50. This ventilation opening 64, 66 is covered by an outlet sealing disk 68, which lies on the base of the bowl 62 and is designed according to fig. 7. It has two openings in the form of segments of a circle, between which the web covering the ventilation opening 64, 66 lies.

The annular wall 72, provided with an external thread, of a lid 74 is screwed into the internal thread of the bowl 62. The lower annular end face of the annular wall 72 is restrained in a sealing manner against the rim of the outlet sealing disk 68. This sealing disk 68 accordingly has a double function by virtue of the fact that, on the one hand, it closes the ventilation opening 64, 66 when there is internal positive pressure in the valve and, on the other hand, it seals the parts 62, 72 screwed to one another.

The lid 74 has a center hole 76 with a recess for a sealing ring 78. The ventilation of the valve interior space is effected via this center opening. Welded in place on the lid 74 is a spring-steel plate 80, from which a blocking spring 82 is stamped and, in the manner which can be seen from fig. 6, is bent in such a way that it overlaps a cutout 84 of the disk 80, this cutout 84 lying above the center

opening 76 of the lid. This blocking spring 82, designed as a leaf spring, carries a blocking pin 86 which is notched in a V-shape and prevents the slamming of the valve by flow pressure, as will be described in detail further below. The blocking pin 86 is connected to the leaf spring 82 via a press-in pin 88, which projects downward into the center opening 76 and interacts with a polished valve ball 90, the valve seat of which is formed by the sealing ring 78.

The housing formed by bowl 62 and lid 74 and enclosing the temperature sensor forms, together with the valve cap 36 and the bellows 46, thermal screening for the temperature sensor and prevents ingress of condensate dripping down and thus premature switching of the snap-disk temperature sensor. This could be realized with only one snap-disk type which keeps the valve open, closes the valve when the control temperature "hot" is reached (venting via the check valve), and only then opens again - protected by the insulated fitting - after sealing (vacuum) and cooling of the container have been effected (in order to prepare the valve for the next use).

The following switching temperatures of the temperature sensor, for example, would be conceivable:

- 134° during heating / 30-50° during cooling: this valve would "function" during every sterilization program which reaches 134°.

Disadvantage: it would not operate if, for example, a 120° program is run (for it would of course then never switch "ON").

- 120° during heating / 30-50° during cooling: this valve would function in a 120° program, and also to a limited extent in a 134° program, although involving risks:
if the valve closes at 120°, a further pressure increase in the gas space of the bellows is no longer possible (only its venting ...); but it is not until 120° that a pressure of 2.1 hPa prevails (saturated-steam curve). If a container is now sterilized in a 134° program, a further pressure increase to 3.2 - 3.4 hPa is effected. This pressure increase (difference is 1.1 - 1.3 hPa) would compress the bellows, and could therefore not penetrate into the container, with the result that either the correct sterilization conditions are not reached inside the container or that the container does not withstand the pressure difference and implodes.

134° and 120° programs are the two standard temperature levels in hospital sterilization. A user therefore ought to

have different valves (for 120° or 134° level) and also ought to attach or exchange these valves before use. This is conceivable, but awkward and susceptible to errors. The snap-disk arrangement described below avoids this disadvantage by the valve being designed in such a way that it can be used at all the common sterilization levels.

The valve ball 90 is carried by a high-grade-steel disk which runs convexly upward in a spherical segment shape and to which it is welded. This high-grade-steel disk 92 retains its shape irrespective of temperature and pressure changes and is displaced merely within the space defined by the annular wall 72 by interacting with the snap disks described below. These snap disks are made of thermobimetal and are characterized in that they switch over into their opposite curvature state at a predetermined heating temperature and, affected by hysteresis, snap back during cooling at a lower switching temperature. In fig. 5, the snap disks described below are depicted in their curvature state which they assume at room temperature. The snap disk 94 adjacent to the high-grade-steel disk 92 is curved in the opposite direction to the steel disk 92 and is upwardly concave. This snap disk 94 typically has the following switch-over temperatures:

during heating, the snap disk 94 snaps over from the concave position into the convex position at 115°C. During

cooling, it snaps back from the convex position into the concave position at 95°C.

Adjacent to the snap disk 94 is a further snap disk 96 having a switching characteristic which is different from the switching characteristic of the snap disk 94. The fitted position of the snap disk 96 corresponds to that of the snap disk 94 and it bears convexly upward in full-face contact with the snap disk 94. The thermobimetal snap disk 96 typically has the following switching temperatures: during heating, it snaps over from the concave position into the convex position at 117°C. During cooling, it snaps back from the convex position into the concave position at 35 to 50°C.

Adjacent to the snap disk 96 is a further high-grade-steel disk 98 which is of upwardly concave design and corresponds to the curvature of the inserted snap disks; it does not change its shape, only its position.

Adjacent to the high-grade-steel disk 98 is a snap disk 94A curved convexly upward and having the same switching characteristic as the snap disk 94. Adjacent to this snap disk 94A is a snap disk 96A which is likewise curved convexly upward and has the same switching characteristic as the snap disk 96. The snap disk 96A is supported by a further dimensionally stable high-grade-steel disk 99 which is curved convexly upward and corresponds in its curvature exactly to the curvature of the snap disks. This high-grade-steel disk

is provided with holes for improving the steam inlet and is supported at the peripheral rim on the outlet sealing disk 68. The intermediate ring 52 forms a shim for providing a distance between the annular flange 48 of the bellows 46 and the valve plate 50 and is connected to these parts in each case in a gas-tight manner by welding, adhesive bonding or screwing.

In the drawing, for the sake of clarity, in each case only the snap disk determining the function is shown. In practice, it may be expedient to use in each case a plurality of identical snap disks fitted in the same direction.

The function of the valve arrangement 24 is described below with reference to figs 4 to 13:

The position of the snap disks which is shown in figs 4 and 5 is maintained during heating up to 115°. At 115°C, the snap disks 94 and 94A switch over into their opposite curvature position according to fig. 10. The overall height and thus the position of the valve ball 90 does not change in the process.

When the second switch-over temperature of 117°C is reached, the snap disks 96 and 96A additionally switch over into their opposite curvature position, as can be seen from fig. 11. The overall height of the stack and the position of the valve ball 90 remain unchanged, so that the valve ring 26 remains lifted from its valve seat 28, i.e. the valve remains

open, so that the media exchange can continue to be effected without hindrance.

According to the invention, measures are taken in order to hold the valve in the open position even when, during the sterilization operation, a flow pressure loads the valve body formed by the valve plate 50, this flow pressure attempting to close the valve against spring preloading. Figs 8 and 9 show that a pressure acting on the valve plate 50 from the bottom upward has displaced the valve plate and the parts carried by it only until the blocking pin 86 held in the inclined position by the spring 82 strikes the step 100 of the valve cap 36. This stop position can be seen from figs 8 and 9. A flow gap between the valve seat 28 and the valve ring 26 is also maintained in this position, so that the media exchange can continue to take place without hindrance. Slamming of the container is therefore reliably prevented, so that any desired loads can be sterilized in sterilizers which are as fast as desired without it being possible for the container to be destroyed.

During the cooling phase, the snap disks 94 and 94A switch over into the position according to fig. 12 at about 95°C, whereas the curvature of the snap disks 96 and 96A still remains unchanged. This results in expanding of the snap-disk stack and thus in lifting of the valve ball 90, which in this position according to fig. 12 bears against the

sealing ring 78 and closes off the valve space from above. During its upward movement, the ball 90 has lifted the blocking pin 96 via the press-in pin 88 and, as can be seen from fig. 12, straightened it up, so that the blocking pin can run freely into the valve cap 36. During the pressure drop in the sterilizer, the external pressure progressively decreases relative to the internal pressure in the container and in the valve space, and pressure compensation is effected via the valve 26, 28, which is still open, it being possible for the pressure compensation inside the valve chamber to be effected via the check valve 58 or the vent opening 56. Further evaporation - and thus vacuum cooling - inside the temperature sensor can now no longer occur, so that premature, undesirable switching of the sensor is reliably prevented.

As soon as the pressure in the sterilizer increases again in the last ventilation phase, the bellows is compressed to an increasing extent as a result of the pressure difference which builds up and the valve 26, 28 is closed, in which case the blocking pin 86, as can be seen from fig. 13, can run into the interior of the valve cap 36. During this operation, the bellows 46 is compressed. This closed position of the valve 26, 28 is maintained during the further cooling and also after removal of the sterilization container from the sterilizer, since a vacuum is maintained

in the interior of the sterilization container and the atmospheric pressure keeps the valve closed. By appropriate dimensioning of the valve gap or of the bellows (cross section and spring rate), the level of the trapped vacuum can be varied within wide limits.

During cooling to their switching temperature (e.g. 35 to 50°C), the snap disks 96, 96A snap over into their opposite curvature position, as a result of which the valve ball 90 is lifted from its seat. In the process, the valve space is ventilated via the ventilation opening 66, but the container interior space is not ventilated. The valve arrangement itself remains in the closed position until the atmospheric pressure can penetrate into the sterilization container via an additional ventilation valve, not shown in the drawing, and a filter connected upstream of the latter. As a result of the spring action of the bellows 46 and due to gravitational force, the valve arrangement then returns into the position according to figs 4 and 5, and the sterilization container can be used for the next sterilization operation without manual manipulation.

A further exemplary embodiment is shown in figs 14 and 15. The function of the valve arrangement shown here corresponds essentially to the function in the case of the embodiment shown according to figs 1 to 13. The valve arrangement is modified compared with the exemplary

embodiment described above inasmuch as a second ball valve is arranged instead of the outlet sealing disk 68. This ball valve consists of a valve-seat ring 104 which is inserted into the ventilation opening 66, is secured by a disk 102 and interacts with a valve ball 106 which is welded to the convexly curved high-grade-steel disk 99. This disk 99 is preloaded by springs 108, as a result of which the valve ball 106 is lifted from its seat. Further springs 110 act on the top high-grade-steel disk 92, as a result of which the valve ball 90 is preloaded in the open position. This causes the ventilation opening 66 to be constantly open while the valve is open. It is not until switch-over is effected into the position according to fig. 15, which corresponds to the position according to fig. 12, that the ventilation opening is closed. The difference compared with the first exemplary embodiment accordingly consists in the fact that, after the switching of the snap disks, the snap-disk housing is completely shut off in both directions.

List of designations

10	Trough
12	Lid
14	Sloping bottom
16	Base frame
18	Sealing ring
20	Groove
22	Perforation holes
24	Valve arrangement
26	Sealing ring, valve ring
28	Valve seat
30	Conical wall section
32	Flat section
34	Hole
36	Valve cap
38	Rotary-lock fastener
40	Circlip
42	Heads
44	Valve-cap flange
46	Bellows
48	Annular flange
50	Valve plate
52	Intermediate ring

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54	Baffle plate
56	Vent opening
58	Sealing disk
60	Leaf spring
62	Bowl
64	Center opening
66	Ventilation opening
68	Outlet sealing disk
70	Openings
72	Annular wall
74	Lid
76	Center opening
78	Sealing ring
80	Spring-steel plate
82	Blocking spring
84	Cutout
86	Blocking pin
88	Press-in pin
90	Valve ball
92	High-grade-steel disk
94, 94A	Snap disk
96, 96A	Snap disk
98	High-grade-steel disk
99	High-grade-steel disk
100	Step

102	Disk
104	Valve-seat ring
106	Valve ball
108	Springs
110	Springs

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Patent claims

1. A sterilization container (10, 12) having a valve arrangement (26; 28) which permits a media exchange inside a sterilizer right into the vacuum drying phase and closes in the last ventilation phase, so that the vacuum prevailing at this instant in the container interior is maintained and the container remains hermetically sealed, the valve arrangement having a valve body (50) subjected to the flow pressure, characterized in that the valve body (50) is prevented from closing by a stop (86, 100), and in that the stop is rendered ineffective before or during the last ventilation phase by the pressure difference which occurs.

2. A sterilization container having a valve arrangement (26; 28) which permits a media exchange inside a sterilizer right into the vacuum drying phase and closes in the last ventilation phase, so that the vacuum prevailing at this instant in the container interior is maintained and the container remains hermetically sealed, the valve arrangement (24) having at least one temperature sensor with hysteresis behavior, characterized in that the temperature sensor is protected from premature cooling by screening (62, 74; 46).

3. The sterilization container as claimed in claim 1 or 2, in which the temperature sensor is formed by a snap-disk stack, characterized in that two snap-disk types (94, 96)

having different temperature behavior are provided in a snap-disk stack.

4. The sterilization container as claimed in one of claims 1 to 3, characterized in that the valve arrangement (26, 28) is arranged as a condensate drain valve at a recessed location of the container bottom.

5. The sterilization container as claimed in claim 4, characterized in that the container bottom has a central wall section (30) running conically upward and having perforation holes (22), and in that the container bottom forms a valve seat (28) in an annular section enclosing the perforation holes (22), this valve seat (28) interacting with a valve body in the form of a valve ring (26) which is carried by a valve plate (50).

6. The sterilization container as claimed in one of claims 1 to 5, characterized in that the valve plate (50), in its center section, carries a housing (62, 72, 74) which accommodates the snap-disk stack (94, 96), which controls a valve ball (90) which interacts with a valve-seat ring (78).

7. The sterilization container as claimed in claim 6, characterized in that the snap-disk housing (62, 72, 74) is enclosed by a bellows (46) which is connected at the lower part to the valve plate (50) and is secured with its top section to a valve cap (36) which in turn is releasably

fastened in the region of a bottom opening (34) of the sterilization container.

8. The sterilization container as claimed in claim 7, characterized in that the valve cap (36) of bowl-like design is put through the bottom opening (34) and releasably fixed there.

9. The sterilization container as claimed in one of claims 1 to 8, characterized in that the lid (74) of the snap-disk housing carries a blocking spring (82) having a blocking pin (86) which, as closing lock of the valve (26, 28), interacts with a valve-cap stop (100).

10. The sterilization container as claimed in claim 9, characterized in that the blocking pin (86) can be shifted into the release position by the valve ball (90) of the snap-disk stack.

11. The sterilization container as claimed in one of claims 1 to 10, characterized in that the base of the snap-disk housing carries an outlet sealing disk (68) which bears as a check valve above a ventilation opening (66) of the valve plate (50).

12. The sterilization container as claimed in one of claims 1 to 11, characterized in that the valve plate, in the space enclosed by the bellows (46), has a vent opening (56) which can be closed as a check valve by a sealing disk (58) preloaded in the sealing position by a leaf spring (60).

13. The sterilization container as claimed in claim 11, characterized in that the snap-disk housing has a bowl-like lower part (62) having an internal thread, into which an annular wall (72) of the lid (74) can be screwed, this annular wall (72) acting with its lower end face against the sealing disk (68).

14. The sterilization container as claimed in one of claims 6 to 13, characterized in that the blocking pin carried by the blocking spring (82) carries the pin (88) which engages in the region of movement of the valve ball (90).

15. The sterilization container as claimed in one of claims 1 to 10, characterized in that the ventilation opening (66) leading into the interior of the snap-disk housing can be closed by a valve ball (106) which is arranged at the base of the snap-disk stack.

16. The sterilization container as claimed in one of claims 1 to 15, characterized in that the valve disk (50) has a conical baffle plate (54) as a condensate deflector under the perforation holes (22) of the container bottom.

17. The sterilization container as claimed in one of claims 2 to 16, characterized in that the snap disks (94, 96) having different temperature characteristics are arranged in pairs and have an identical curvature configuration at room temperature.

18. The sterilization container as claimed in claim 17, characterized in that two snap-disk pairs (94, 96), of which one pair is curved concavely upward and the other pair is curved convexly upward, are arranged in the snap-disk housing.

19. The sterilization container as claimed in claims 17 and 18, characterized in that a high-grade-steel disk (92) curved convexly upward and having an invariable curvature lies above the upper snap-disk pair (94, 96) and carries the valve ball (90) in the center part.

20. The sterilization container as claimed in claims 17 to 19, characterized in that the lower snap-disk pair (94A, 96A) is supported by a high-grade-steel disk (99) which is curved convexly upward and is invariable in its shape, and in that a high-grade-steel disk (98) curved concavely upward lies between the snap-disk pairs (94, 96, 94A, 96A).

21. The sterilization container as claimed in one of claims 17 to 20, characterized in that the respectively upper snap disk (94, 94A) of each snap-disk pair has a snap-over point at about 115°C during heating and snaps back under hysteresis at 95°C during cooling.

22. The sterilization container as claimed in one of claims 17 to 21, characterized in that the respectively lower snap disk (96, 96A) of each snap-disk pair has a snap-over point of more than 115°C, preferably 117°C, during heating and does

not snap back under hysteresis until 35 to 50°C during cooling.

23. The sterilization container as claimed in one of claims 15 and 17 to 22, characterized in that the valve ball (106) interacting with the ventilation opening (66) is carried by the lower high-grade-steel disk (99).

24. The sterilization container as claimed in one of claims 1 to 23, characterized in that a distance piece (52) is provided between a lower annular flange (48) of the bellows (46) and the valve plate (50).

25. The sterilization container as claimed in claim 1 or 2, characterized in that a sealing ring (18) of L-shaped cross section is arranged between container lid (12) and trough (10), this sealing ring (18) being inserted with its radially inwardly disposed leg into a circumferential groove (20) of the container lid and interacting with a radial and horizontal annular surface of the trough top rim.

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Internationales Büro

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Mit internationalem Recherchenbericht.

Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist; Veröffentlichung wird wiederholt falls Änderungen eintreffen.

(54) Title: STERILIZATION CONTAINER

(54) Bezeichnung: STERILISIERBEHÄLTER

(57) Abstract

The invention relates to a sterilization container with a valve arrangement that is designed in such a manner that the valve intended for the exchange of media remains open right into the venting phase and is then closed before the pressure difference is compensated for at a predetermined differential pressure and remains closed until the container is opened for the purpose of withdrawing and using the instruments contained therein. The valve is actuated via a snap disk arrangement, the snap disks of which vault gradually into the opposite direction at predetermined temperatures, thereby effecting a defined valve control. A premature back-switching of certain snap disks that could be caused by a cooling-off as a result of the evaporation of the condensate is prevented by accommodating the snap disk arrangement in a thermally insulated housing.

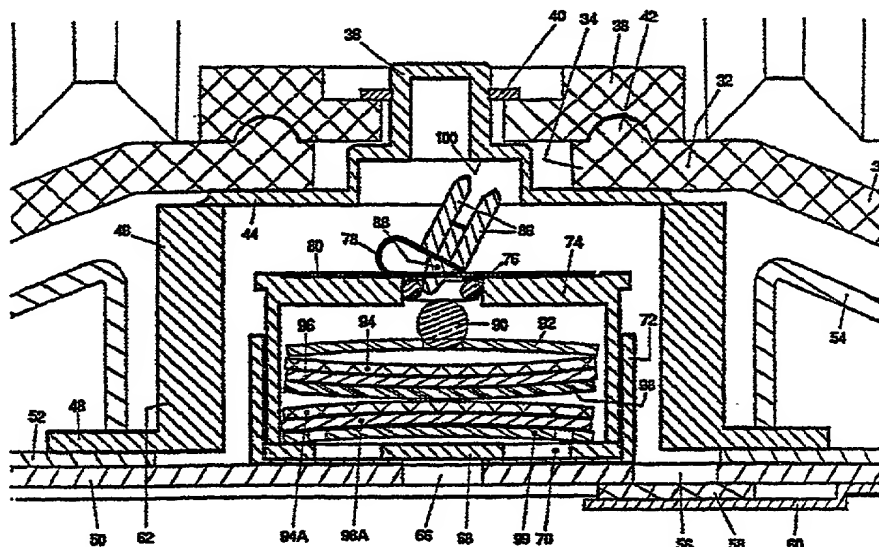


FIG. 1

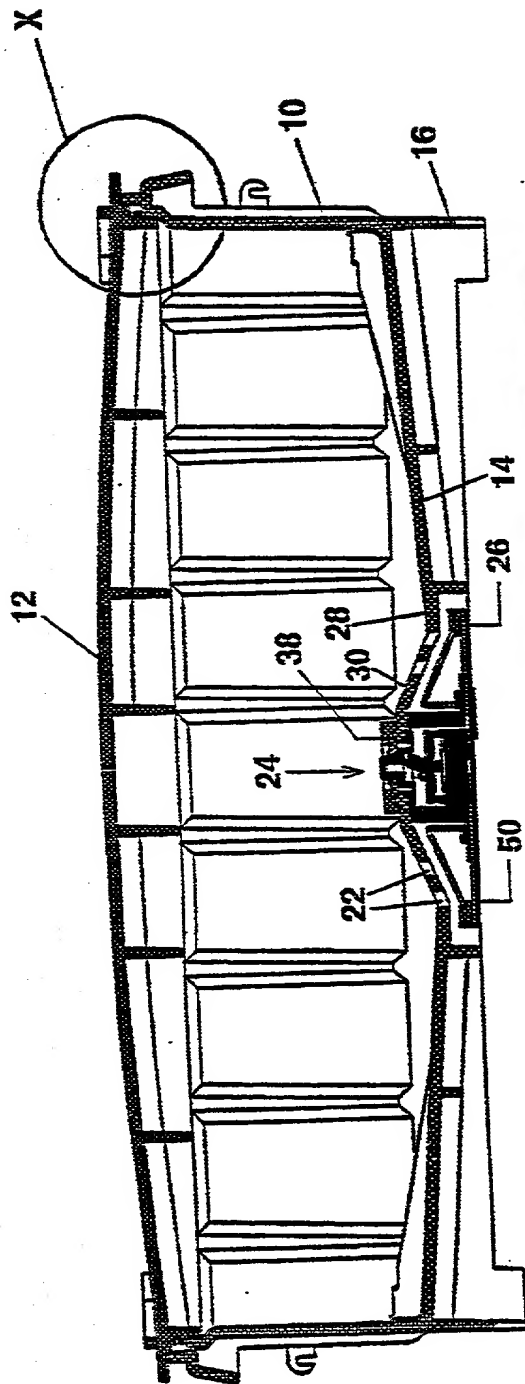
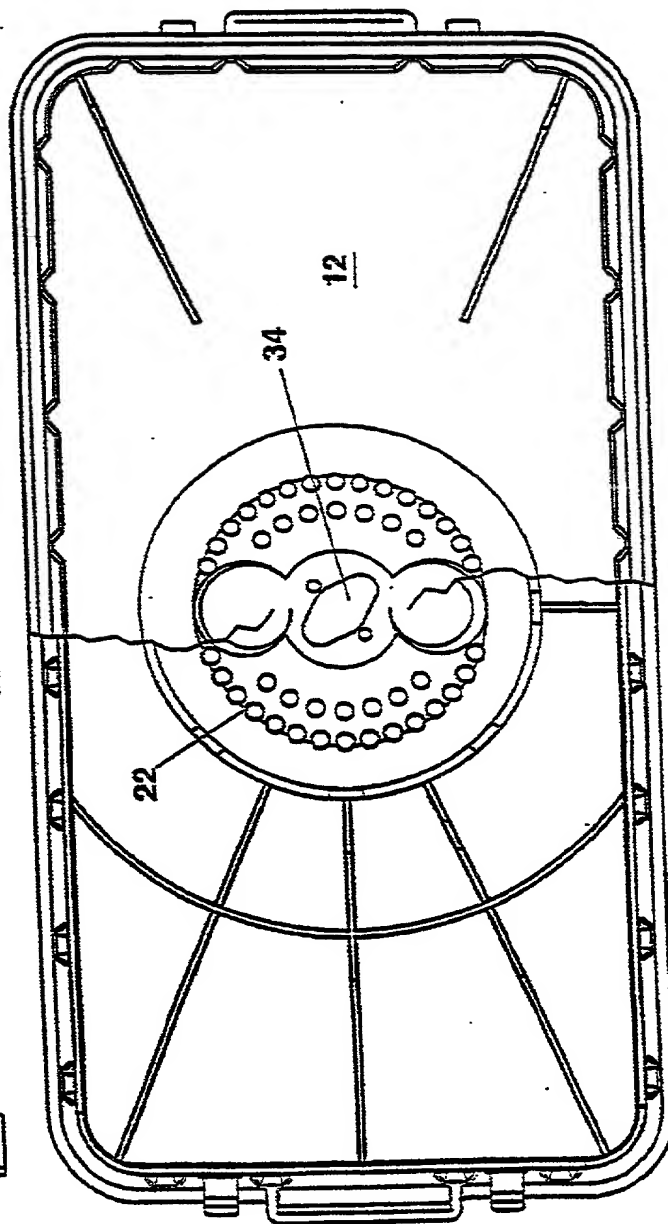
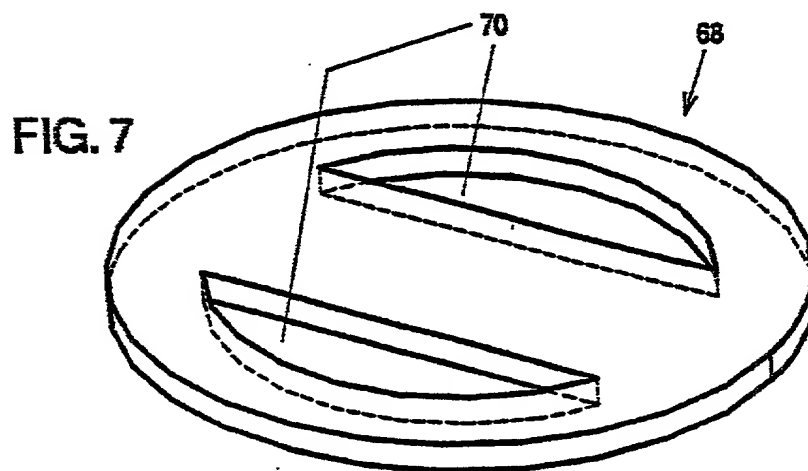
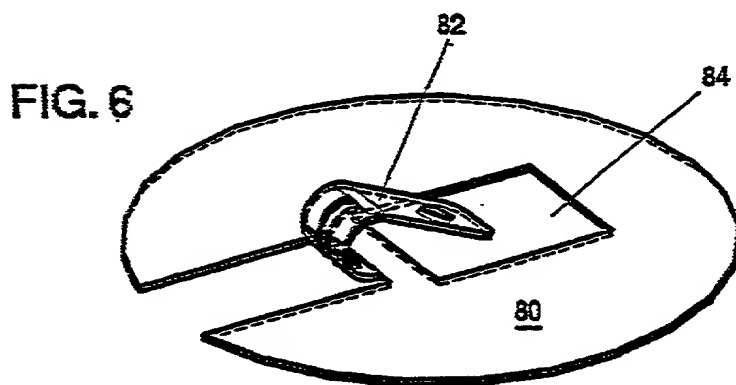
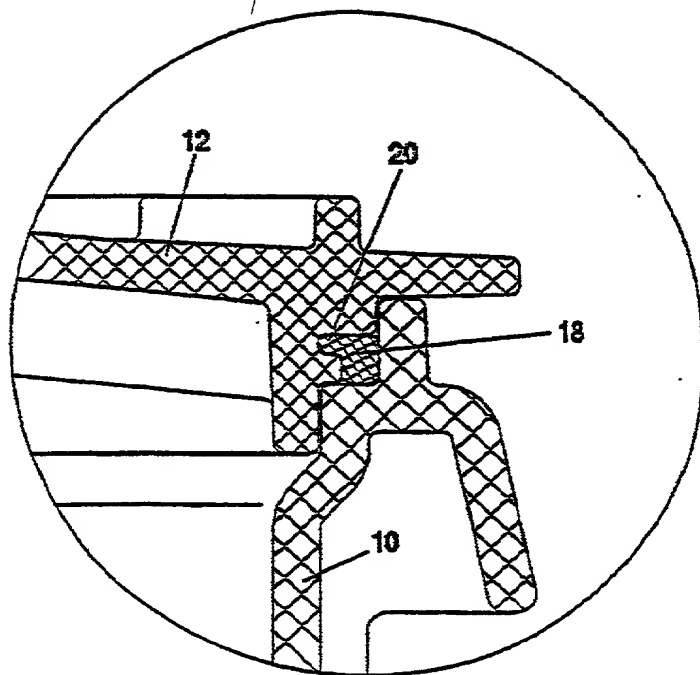


FIG. 2



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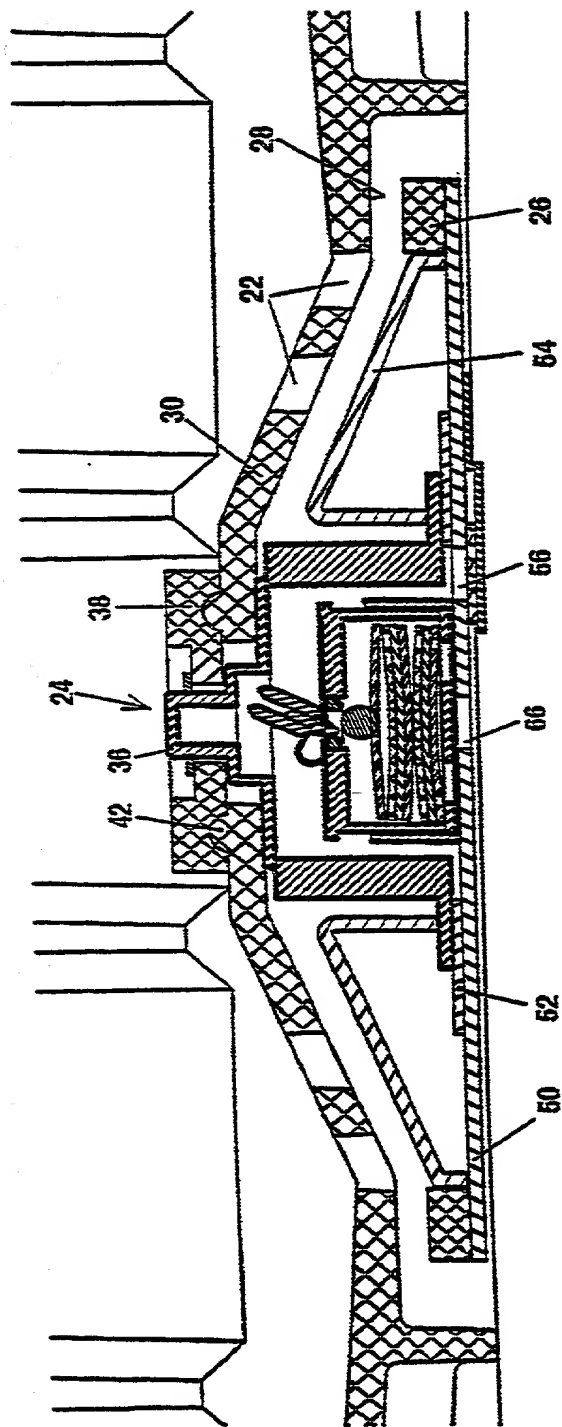


FIG. 4

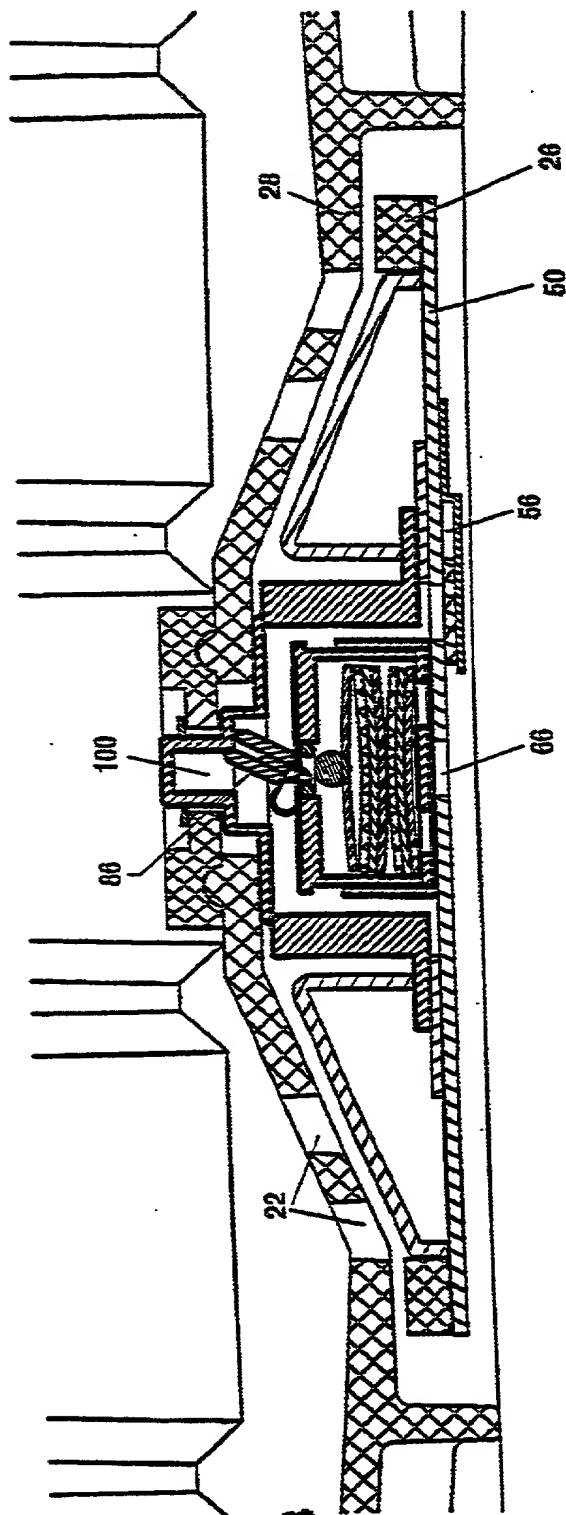
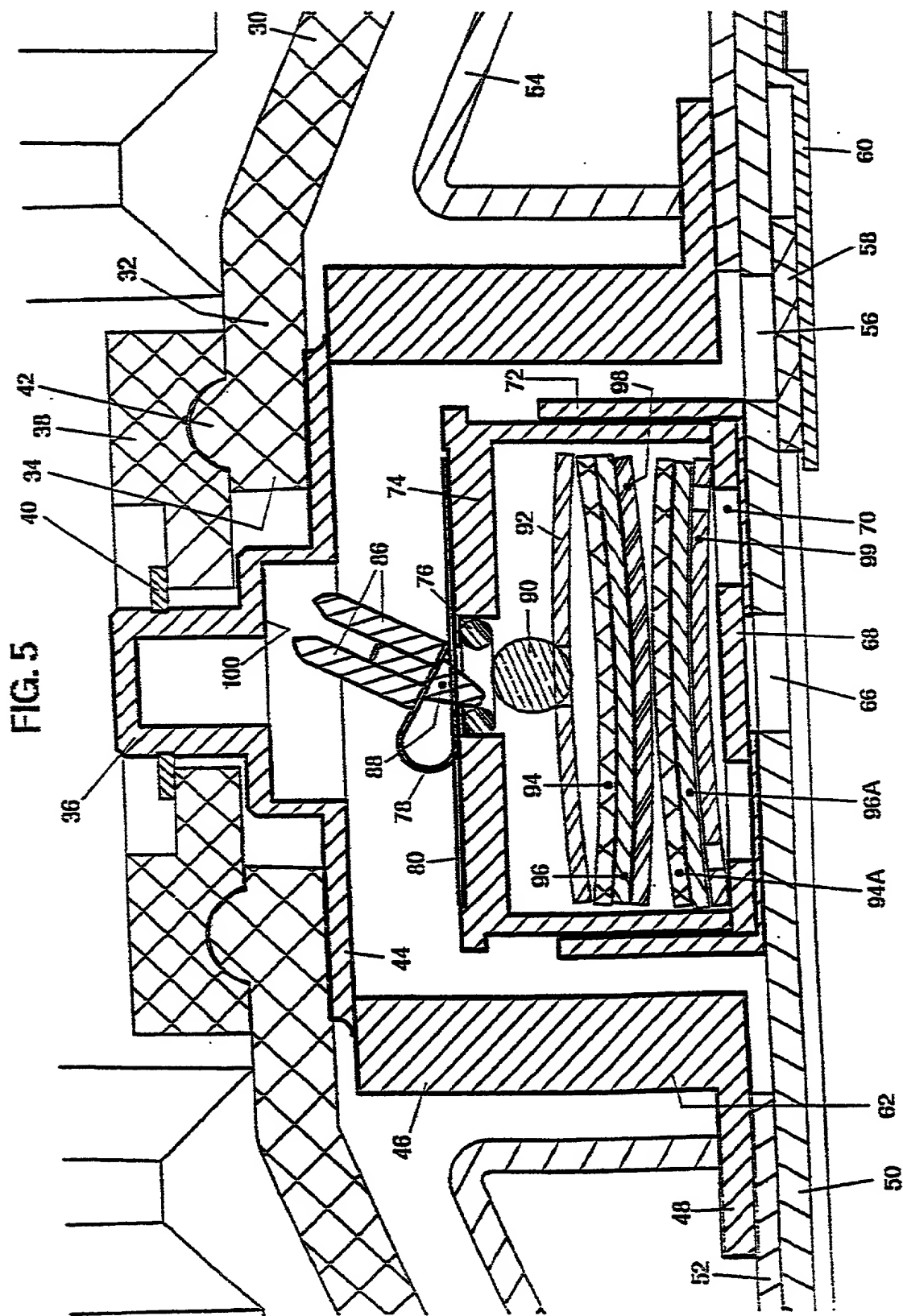


FIG. 8



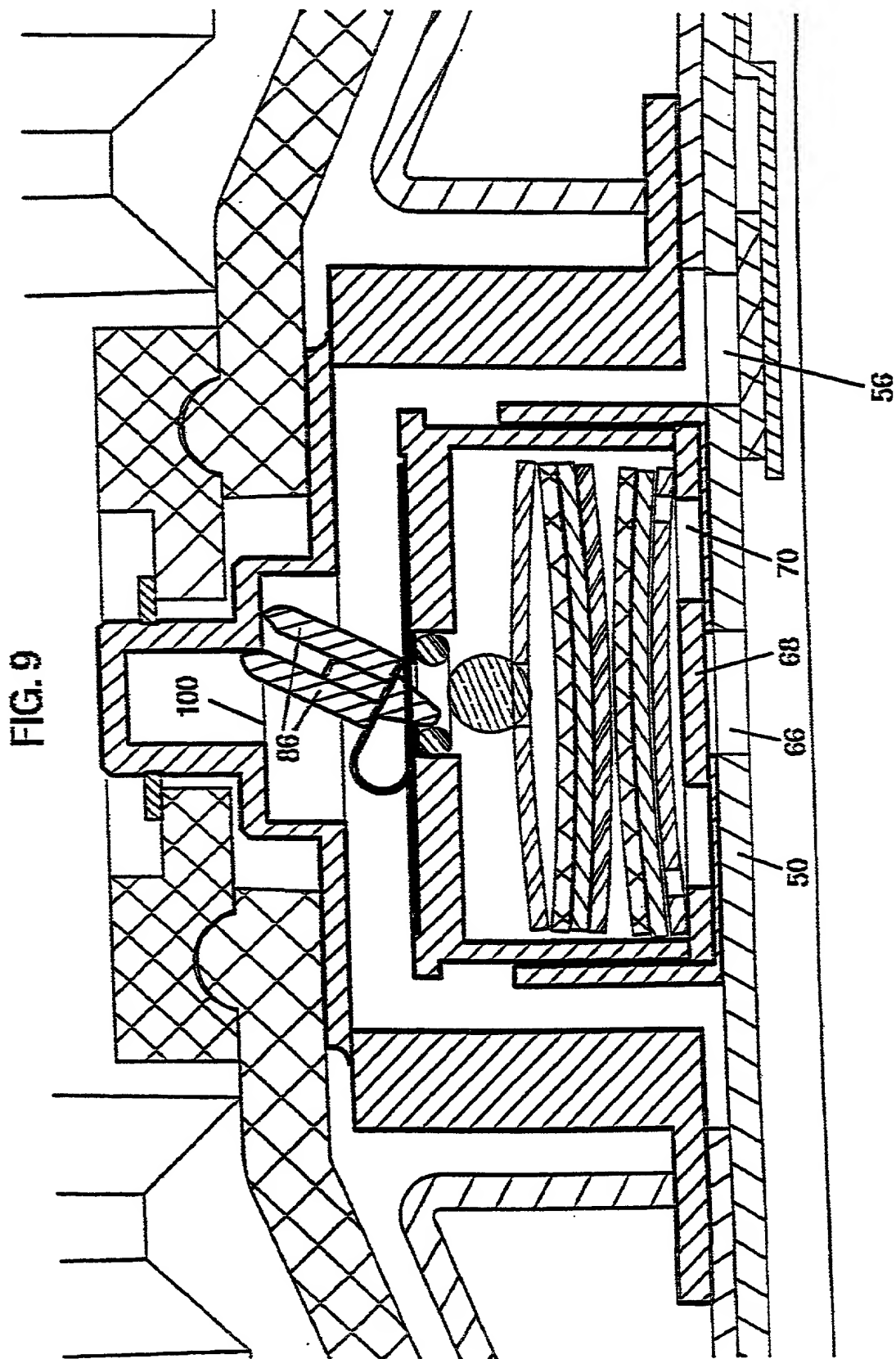


FIG. 10

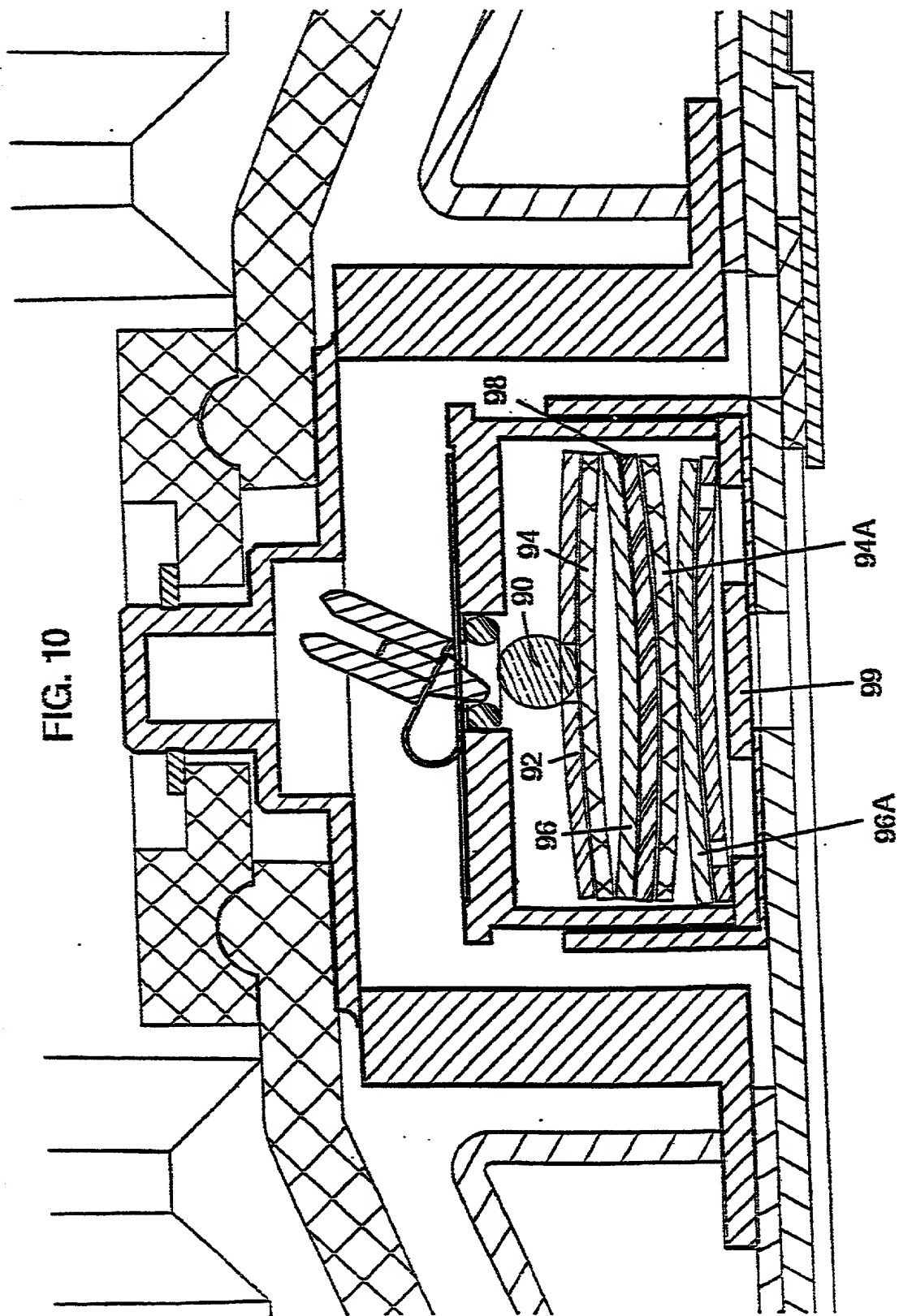


FIG. 11

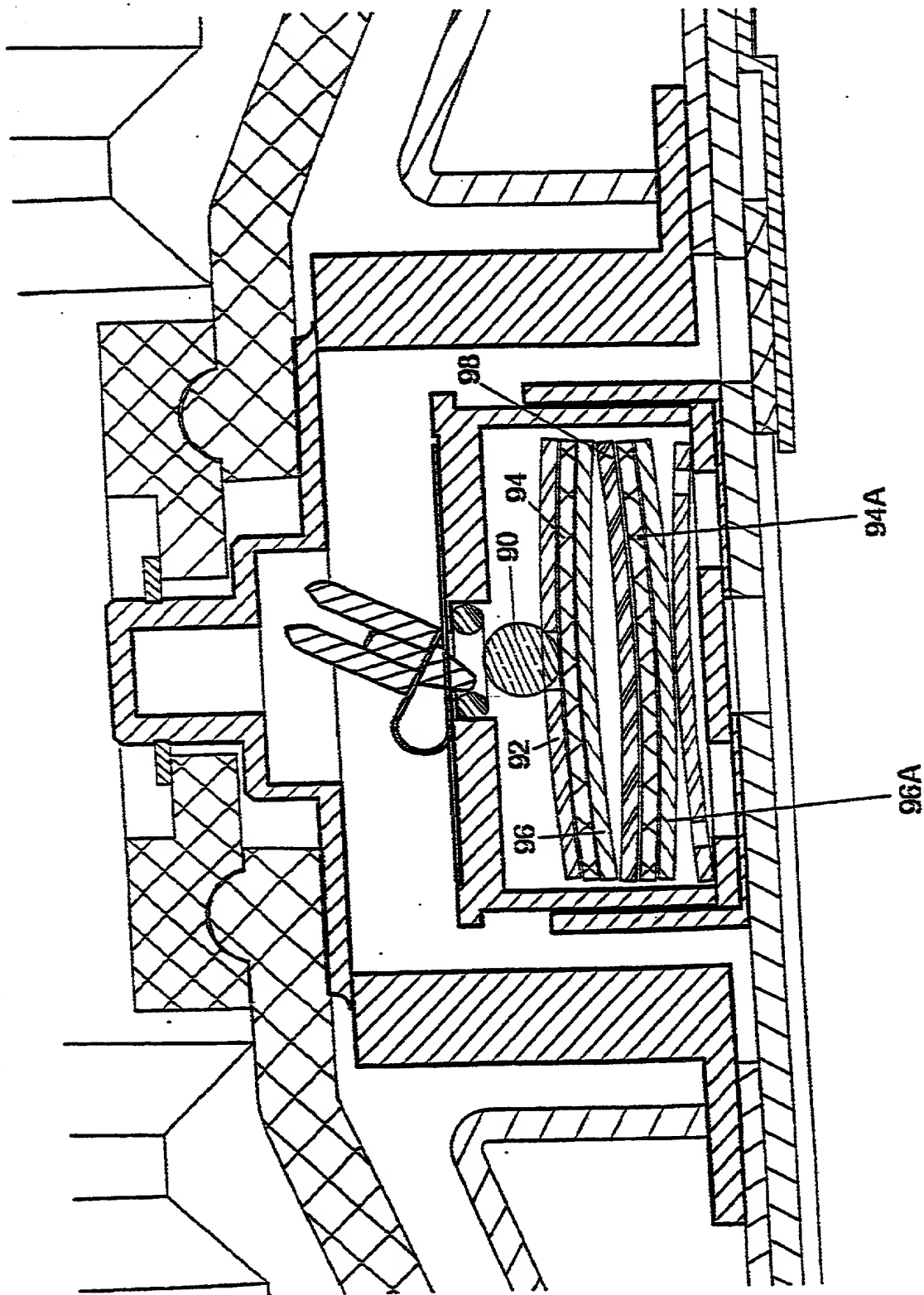


FIG. 12

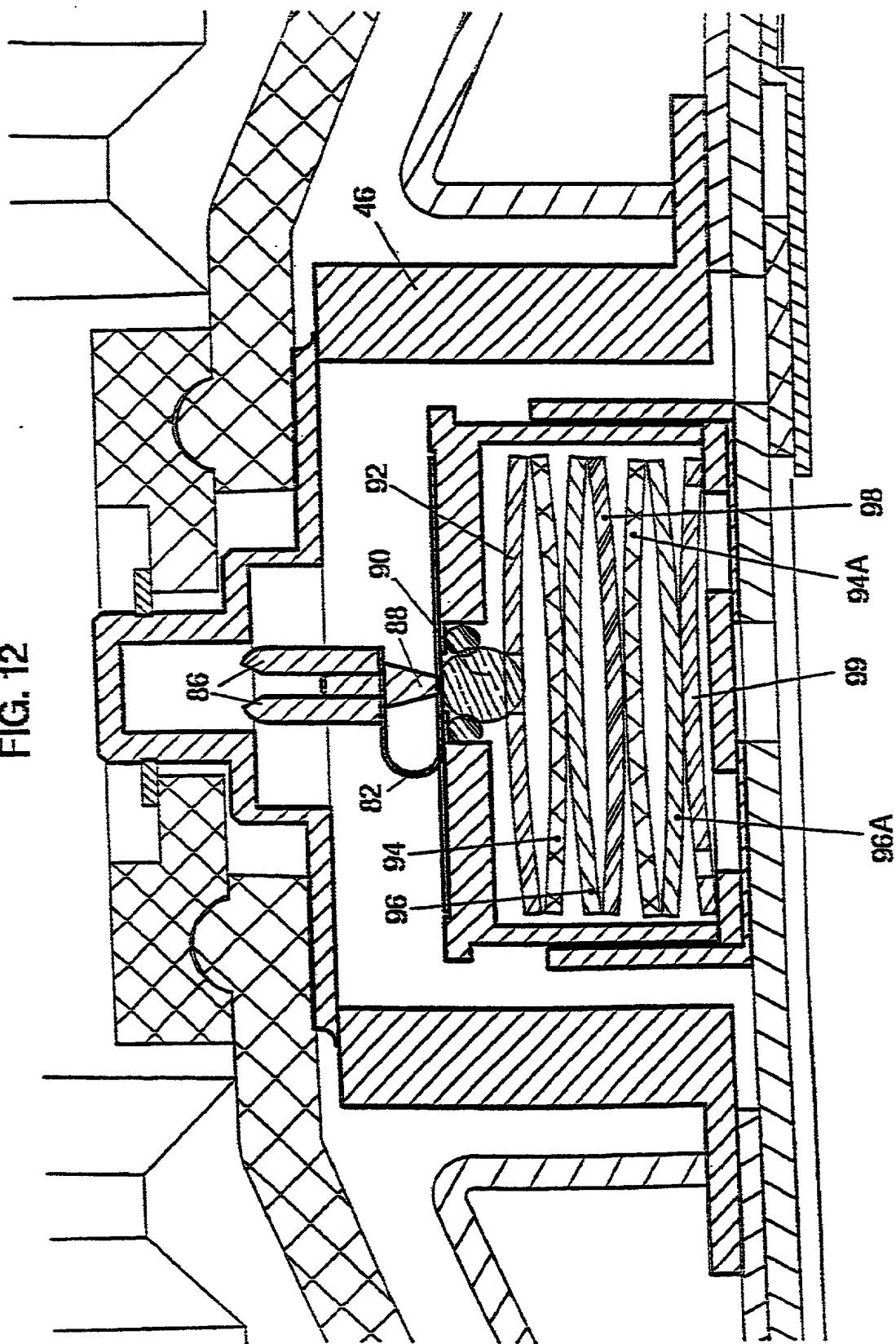


FIG. 13

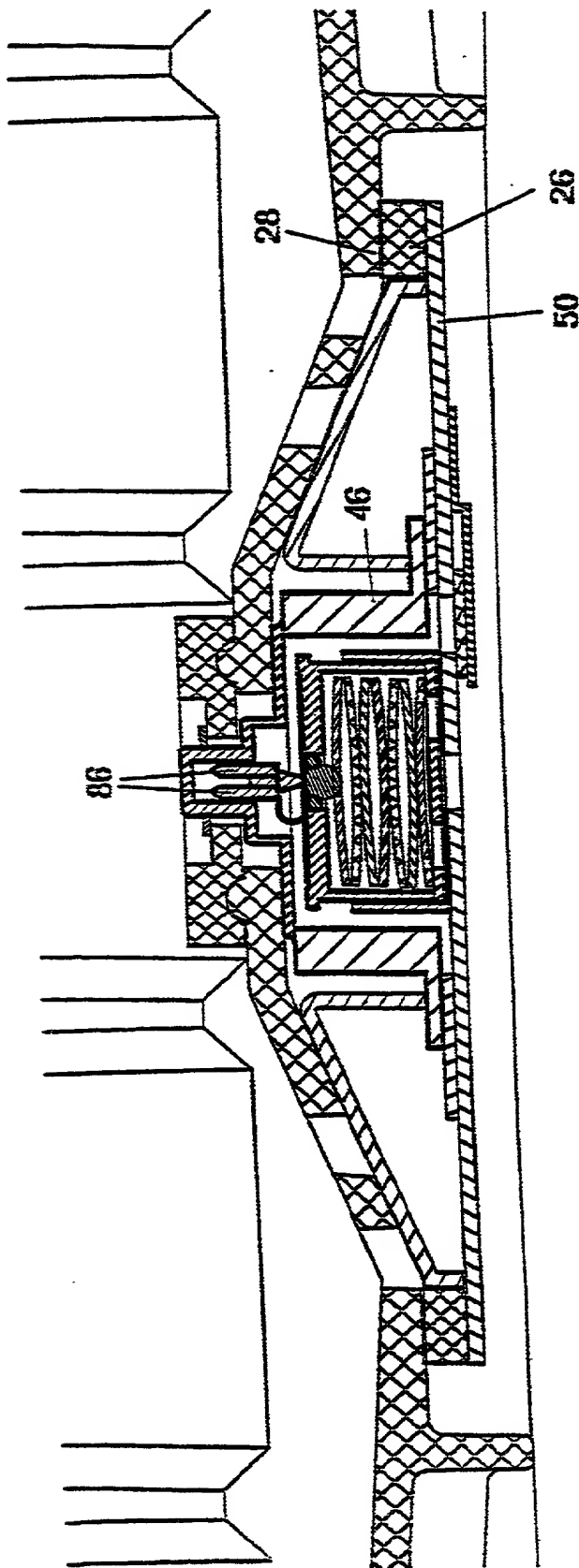


FIG. 14

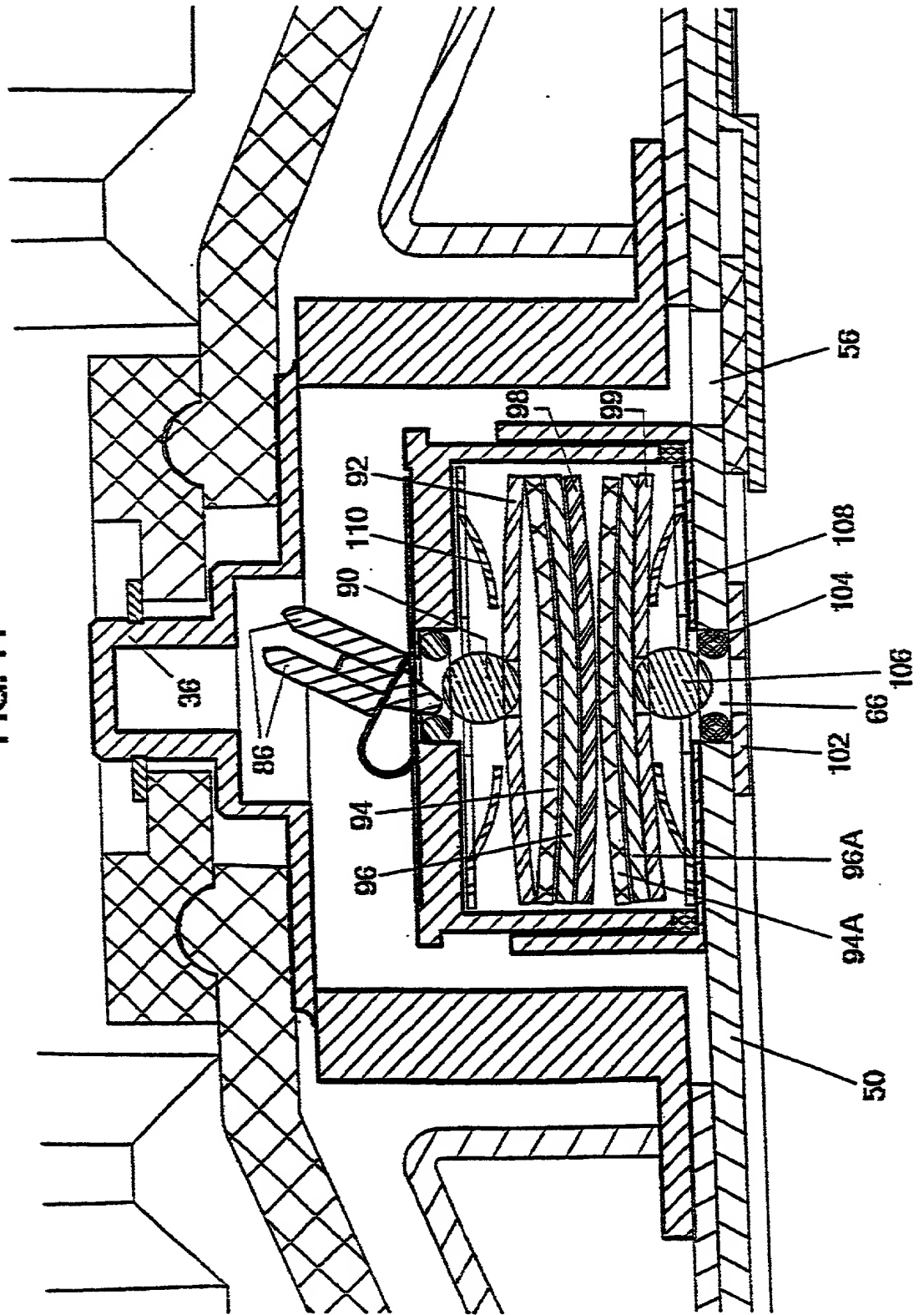
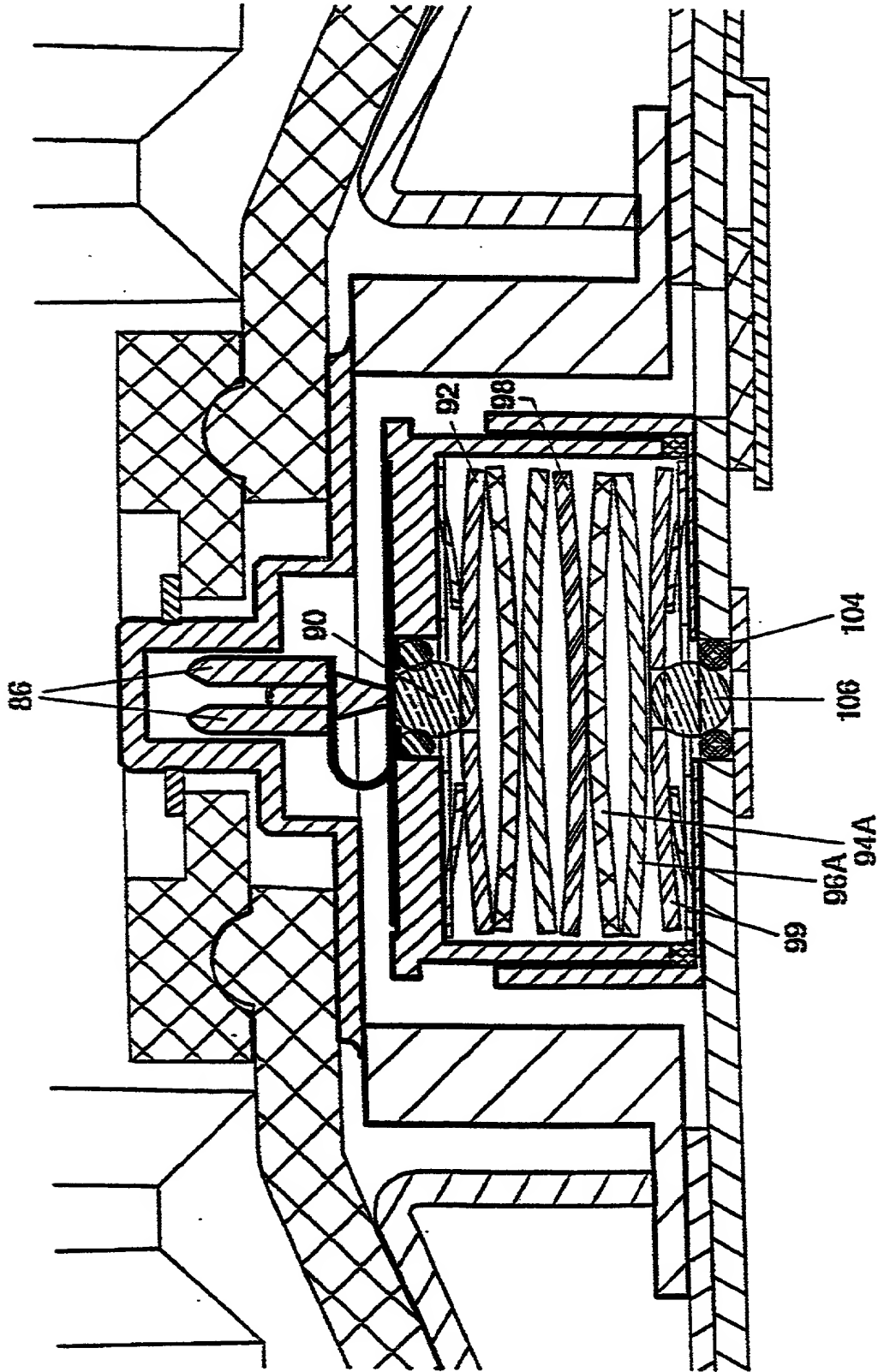


FIG. 15



UNITED STATES OF AMERICA
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P/37-171

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I verily believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

STERILIZATION CONTAINER

the specification of which is attached hereto, unless the following box is checked:

☒ was filed on 21 March 2000 as United States patent Application Number or PCT International patent application number PCT/EP00/02502 and was amended on _____ (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information known to be material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate or United States provisional application(s) listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign or Provisional Application(s)

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C. 119
Germany	199 13 417.0	25 March 1999	YES <u>X</u> NO _____
			YES _____ NO _____

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

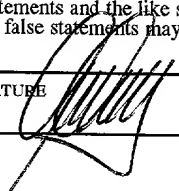
UNITED STATES APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby appoint customer no. 2352 OSTROLENK, FABER, GERB & SOFFEN, LLP, and the members of the firm, Samuel H. Weiner - Reg. No. 18,510; Jerome M. Berliner - Reg. No. 18,653; Robert C. Faber - Reg. No. 24,322; Edward A. Meilman - Reg. No. 24,735; Steven I. Weisburd - Reg. No. 27,409; Max Moskowitz - Reg. No. 30,526; Stephen A. Soffen - Reg. No. 31,063; James A. Finder - Reg. No. 30,173; William O. Gray, III - Reg. No. 30,944; Louis C. Dujmich - Reg. No. 30,625; Douglas A. Miro - Reg. No. 31,643, and Michael J. Scheer - Reg. No. 34,425, as attorneys with full power of substitution and revocation to prosecute this application, to transact all business in the Patent & Trademark Office connected therewith and to receive all correspondence.

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FULL NAME OF SOLE OR FIRST INVENTOR Peter WAGNER INVENTOR'S SIGNATURE  DATE OCT 12, 2001

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FULL NAME OF SECOND JOINT INVENTOR (IF ANY) _____ INVENTOR'S SIGNATURE _____ DATE _____

RESIDENCE (City and either State or Foreign Country) _____ COUNTRY OF CITIZENSHIP _____

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